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K012773

VIII. 510(k) Summary

NOV 1 6 2001

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SUBMITTER:	DePuy AcroMed™, Inc. 325 Paramount Drive Raynham, MA 02780
CONTACT PERSON:	Karen F. Jurczak
DATE PREPARED:	August 17, 2001
CLASSIFICATION NAME:	System, Facet Screw Spinal Device
PROPRIETARY NAME:	DISCOVERY Facet Screw
PREDICATE DEVICES:	Preamendment Townley Bone Graft Screw Townley Transfacetpedicular Screw System (K003928) Townley Transfacet/Intrapedicular Screw (K994308)
INTENDED USE:	The Discovery Facet Screw Fixation System is intended to stabilize the spine as an aid to fusion by two different fixation methods: Transfacet fixation - The screws are inserted bilaterally through the superior side of the facet, across the facet joint and into the inferior pedicle. Translaminar-facet fixation - The screws are inserted bilaterally through the lateral aspect of the spinous process, through the lamina, through the superior side of the facet, across the facet joint and into the inferior pedicle. For both methods, this system is indicated for the posterior surgical treatment of any or all of the following at the L1 to S1 (inclusive) spinal levels: 1) Trauma, including spinal fractures and/or dislocations; 2) Spondylolisthesis; 3) Spondylolysis; 4) Pseudoarthrosis or failed previous fusions which are symptomatic or which may cause secondary instability or deformity; 5) Degenerative diseases which include: (a) degenerative disc disease (ddd) as defined by neck and/or back pain of discogenic origin as confirmed by patient history with degeneration of the disc as confirmed by radiographic studies and/or (b) degenerative disease of the facets with instability
MATERIALS:	Manufactured from ASTM F-136 implant grade titanium alloy.

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DESCRIPTION:

The Discovery Facet Screw Fixation System consists of screws and washers designed to compress bone grafts and/or fractures. The screws are intended only for use in combination with the washer. The system includes two screw styles: fully threaded and lag.

The DISCOVERY Facet Screw is a broad-headed screw that is designed to compact or stabilize adjacent facet articular processes to enhance spinal fusion and stability. The system is intended to stabilize the spine as an aid to fusion through bilateral immobilization of the facet joints. The screws are inserted posteriorly through the superior side of the facet, across the facet joint, and into the pedicle.

PERFORMANCE DATA:

Biomechanical testing, including static and fatigue 3-Point Bend Testing and Cantilever Testing, were conducted.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Mr. Frank Maas
Manager, Regulatory Affairs
DePuy Acromed, Inc.
325 Paramount Drive
Raynham, Massachusetts 02767

NOV 1 6 2001

Re: K012773
Trade/Device Name: Discovery Facet Screw Fixation System
Regulatory Number: N/A
Regulation Name: N/A
Regulatory Class: unclassified
Product Code: MRW
Dated: August 17, 2001
Received: August 20, 2001

Dear Mr. Maas:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

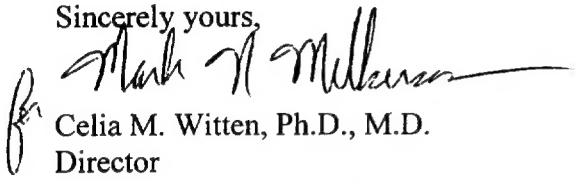
If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the current Good Manufacturing Practice requirement, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic (QS) inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a

legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4659. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or at (301) 443-6597, or at its Internet address "http://www.fda.gov/cdrh/dsmamain.html".

Sincerely yours,



Celia M. Witten, Ph.D., M.D.
Director
Division of General and
Restorative Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

IV. Indications for Use

510(k) Number (if known): K012773

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Device Name: DISCOVERY Facet Screw Fixation System

Indications For Use:

The Discovery Facet Screw Fixation System is intended to stabilize the spine as an aid to fusion by two different fixation methods:

Transfacet fixation - The screws are inserted bilaterally through the superior side of the facet, across the facet joint and into the inferior pedicle.

Translaminar-facet fixation - The screws are inserted bilaterally through the lateral aspect of the spinous process, through the lamina, through the superior side of the facet across the facet joint and into the inferior pedicle.

For both methods, this system is indicated for the posterior surgical treatment of any or all of the following at the L1 to S1 (inclusive) spinal levels: 1) Trauma, including spinal fractures and/or dislocations; 2) Spondylolisthesis; 3) Spondylolysis; 4) Pseudoarthrosis or failed previous fusions which are symptomatic or which may cause secondary instability or deformity; 5) Degenerative diseases which include: (a) degenerative disc disease (ddd) as defined by neck and/or back pain of discogenic origin as confirmed by patient history with degeneration of the disc as confirmed by radiographic studies and/or (b) degenerative disease of the facets with instability

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Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use: X OR Over-The-Counter Use: _____
(Per 21 CFR 801.109)

for Mark N Milhous

(Division Sign-Off)
Division of General, Restorative
and Neurological Devices

510(k) Number K012773